SODIUM CHLORIDE- sodium chloride injection, solution Baxter Healthcare Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

0.9% SODIUM CHLORIDE INJECTION

HEALTH CARE PROVIDER LETTER



Important Prescribing Information

October 21, 2024

Subject: Temporary importation of 0.9% Sodium Chloride Injection, 5% and 10% Glucose Injection, and 5% Glucose/0.9% Sodium Chloride Injection from Shanghai, China, labeled in English to address drug shortages

Dear Healthcare Professional,

To prevent a drug shortage of large volume parenteral fluid drug products, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Injection (250 mL and 1,000 mL), 5% Glucose Injection (250 mL and 1,000 mL), 10% Glucose Injection (250 mL), and 5% Glucose/0.9% Sodium Chloride Injection (1,000 mL) from Baxter's manufacturing facility in Shanghai, China. FDA has not approved these products manufactured by Baxter's Shanghai facility.

You may be provided with additional letters for other imported products you receive. Please read each letter in its entirety because each letter may contain different, product specific information.

At this time, no other entity except Baxter is authorized by the FDA to import or distribute these products in the United States.

Effective immediately, and during this temporary period, Baxter will offer the following imported products:

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
	250 mL	A6C1322US	40	0338-9791-01
0.9% Sodium Chloride Injection	500 mL	A6C1323US	24	0338-9808-01
	1,000 mL	A6C1324US	12	0338-9793-01
EW Characteristics	250 mL	A6C0062US	40	0338-9795-01
5% Glucose Injection	1,000 mL	A6C0064US	12	0338-9801-01
10% Glucose Injection	250 mL	A6C0162US	40	0338-9797-01
5% Glucose/0.9% Sodium Chloride Injection	1,000 mL	A6C1064US	12	0338-9799-01

It is important to note the following:

After opening the carton or box, the bags should be inspected visually to confirm there is no visible particulate
matter or bag defects, such as leaks. Container integrity is imperative to ensure sterility of products listed in the
table above. Parenteral drug products should be inspected visually for particulate matter and bag defects prior to
administration, whenever solution or container permits.

USE A NEW BAG IF PARTICULATES ARE VISIBLE OR IF THE IV BAG CONTAINS A LEAK.

- The imported products' administration port system is fully compatible with Baxter sets marketed in the United States.
- The products listed in the table above contain black barcodes (versus the white barcode on the approved
 product) and the barcode has been placed in a different position. The barcode on the imported product is
 encoded with the National Drug Code (NDC) that is specific to the imported product. However, the barcodes may
 not register accurately in the U.S. scanning systems. Institutions should manually input the product into their
 systems to ensure that barcode systems do not provide incorrect information when the product is scanned.
 Alternative procedures should be followed to ensure that the correct drug product is being used in all systems
 and processes and administered to individual patients
- The 250 mL product is compatible for admixing with Baxter's Vial-mate product.
- The imported product uses a carton box that is taped closed. To avoid damage to the solution container, take
 care not to use sharp instruments to open the carton.
- Dextrose, USP is a hydrated form of glucose. The imported glucose product is an anhydrous form of glucose.
 Therefore on an energy content per mL basis,
 - 5% Glucose/0.9% Sodium Chloride Injection (0.20 kcal/mL) is <u>NOT</u> equivalent to 5% Dextrose and 0.9%
 Sodium Chloride Injection USP (0.17 kcal/mL),
 - 5% Glucose Injection (0.20 kcal/mL) is NOT equivalent to 5% Dextrose Injection USP (0.17 kcal/mL),
 - 10% Glucose Injection (0.40 kcal/mL) is NOT equivalent to 10% Dextrose Injection USP (0.34 kcal/mL).
- The imported glucose containing products are <u>NOT</u> directly interchangeable with dextrose containing
 injections USP. Protocols, order entry, and compounding systems will need to be adjusted.
- 0.9% Sodium Chloride Injection USP, 5% Dextrose Injection USP, 10% Dextrose Injection USP, and 5%
 Dextrose/0.9% Sodium Chloride Injection USP are available only by prescription in the U.S. However, the
 imported products do not have the statement "Rx only" on the labeling.

Additional key differences in the labeling between the FDA-approved products and the imported products are stated in the product comparison tables at the end of this letter as follows:

- Table 1 Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP
- Table 2 Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP
- Table 3 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection
- Table 4 Label images of FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection
- Table 5 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection
- Table 6 Label images of FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection
- Table 7 Key differences between FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium Chloride Injection

Table 8 Label images of FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium Chloride Injection

Reporting Adverse Events or Product Quality Issues

To report adverse events associated with these imported products, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use of these imported products may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form <u>www.fda.gov/MedWatch/getforms.htm</u> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

To report product quality issues associated with these imported products, please contact Baxter Product Surveillance through Baxter - Product Feedback Portal (https://productfeedback.baxter.com/).

Please also refer to the local prescribing information of the imported product, translated into English, available for:

- . 0.9% Sodium Chloride Injection (click here)
- . 5% Glucose Injection (click here)
- 10% Glucose Injection (click here)
- 5% Glucose/0.9% Sodium Chloride Injection (click here)

Please refer to the FDA-approved prescribing information for each drug product listed below:

- 0.9% Sodium Chloride Injection USP (click here)
- 5% Dextrose Injection USP (click here)
- 10% Dextrose Injection USP (click here)
- 5% Dextrose/0.9% Sodium Chloride Injection USP (click here)

If you have any questions about the information contained in this letter or the use of the imported products, please contact Baxter's Medical Information Service at 1-800-933-0303.

To place an order, please contact Baxter's Center for Service at 1-888-229-0001.

Sincerely,

Lee Ann Schuette
Lee Ann Schuette
Lee Ann Schuette

Lee Ann Schuette

VP Global and US Marketing IV solutions, Clinical Nutrition, Pharmacy Tools

Baxter Healthcare Corporation

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Product Comparison Table

Table 1 Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP

3	FDA-approved product	Imported product from Shanghai, China
Product name	0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection
Label volume	100 mL; 150 mL; 250 mL; 500 mL; 1000 mL	250 mL; 500 mL; 1000 mL
Language of the Labels	English	English
Indications	Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.	Sodium Chloride Injection is indicated as a source of water and electrolytes.
Active ingredients	Each 100 mL contains 900 mg Sodium Chloride, USP	Each 100 mL contains 900 mg Sodium Chloride
Additional information	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
Medication and Administration port closures	Contains medication port and administration port; Pull off port protector (blue color), right side	Contains medication port and administration port; Twist off port protector (white color), left side

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Table 2 Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP

FDA-approved product	Imported product from Shanghai, China		
0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection		
Label Color: Black. Barcode not shown. 1000 mL shown as representative label.	Label Color: Black. 1000 mL shown as representative label. Imported product contains NDC number, which is not yet shown below. Barcode location is shown will contain a linear barcode with human readable information.		
⊙ ⊙ NDC 0338-0019-04 1	100 Baxter [®] A6C1324US		
0.9% Sodium $\overline{2}$	200 SODIUM CHLORIDE INJECTION		
Chloride $\overline{3}$ Injection USP	1000ml (0.9%)		
1000 mL 4	400 Sodium Chloride		
EACH 100 mL CONTAINS 900 mg SORIUM CHLORIDE USP pH 5.0 (4.5 to 7.0) mEgit. Social 154 CHLORIDE 154 OMERICATE 308 MODIFIDIO (50xC) STIRBLE NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACEST IF ANALARIE WHIS INTRODUCING ADDITIVES USE ASSEPTIC TECHNOLISE MIX TRODUCING ADDITIVES USE ASSEPTIC TECHNOLISE MIX TRODUCING ADDITIVES	[Strength] 1000ml; 9g [Description] This product is a clear, coloriess liquid [Desage and Administration] Intravenous drip. See the package insert for details. For details of [Indications], [Adverse Reactions],		
STORE DOSAGE INTRAVENCIELY AS DIRECTED BY A PHYRICIAN SEE DIRECTIONS CAUTIONS SOLREER AND INSPECT INNERS MAD RESIDENT AND STREET STREAM THE POLYAGE AND THE LIBERT STREAM THE POLYAGE MADE TO THE LUESD IN SERVES CONNICTIONS	[Contraindications], and [Precautions], please refer to the package insert. [Storage] Store in overwrap The solution should be clear and should be used		
CLEAN TX ONLY STORE UNIT IN MODIFILE BARRIER OVERWARD AT ROOM TEMPRISHING (25°C/27°F) UNITS, MEADY TO USE AVOID EXCESSIVE HEAT SEE NEETH	up at one time Inspect the inner bag by squeezing it and discard solution if leakage occurs License Number: H19983149		
VIAFLEX CONTAININ BRATTEN VANILEX, AND PL 146 AND TRACEMANGS OF BRATTEN INTERNATIONAL INC.	[Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. 800 Address: No. 388, Tingzhu Road, Jinshan District, Shanghai		
FOR PRODUCT INFORMATION 1-800-933-0303	GTIN Barcode Area		
BAXTER HEALTHCARE CORPORATION DEEMPILD IL 60015 USA	900 LOT		
Made in USA	MFG		
9	EXP		

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Table 3 Key differences between FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection

	FDA-approved product	Imported product from Shanghai, China
Product name	5% Dextrose Injection USP	5% Glucose Injection
Label volume	250 mL, 1000 mL	250 mL, 1000 mL
Language of the Labels	English	English
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	Glucose Injection is indicated as a source of water and calories.
Active ingredients	Each 100 mL contains 5 g Dextrose Hydrous USP	Each 100 mL contains 5 g Anhydrous Glucose
Additional	pH 4.0 (3.2 to 6.5)	4.0 (3.2 to 6.5)
information	Osmolarity 252 mOsmol/L (calc)	Osmolarity 278 mOsmol/L (calc)
Caloric content	170 kcal/L	200 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
Medication and Administration port closures	Contains medication port and administration port; Pull off port protector (blue color), right side	Contains medication port and administration port; Twist off port protector (white color), left side

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Table 4 Label images of FDA-approved 5% Dextrose Injection USP and imported 5% Glucose Injection

FDA-approved product		Imported product from Shanghai, China		
5% Dextrose Injection USP	5% Dextrose Injection USP 5% Glucose Injection			
Label Color: Black. Barcode not shown. 1000 mL shown as representative label.		Label Color: Black. 1000 mL shown as representative label. Imported product contains th NDC number, which is not yet shown below. Barcode location is show and will contain a linear barcode with human readable information.		
② 280064 NDC 0338-0017-04	ī	100 Baxter® A6C0064US		
5% Dextrose	<u>2</u>	200 GLUCOSE INJECTION		
Injection USP	<u>3</u>	300 5%		
1000 mL EACH 100 mL CONTAINS 5 g DEXTROSE HYDROUS USP pH 4.0 (3.2 TO 6.5) OSMOLARITY 252	7	400 1000ml GLUCOSE		
mOsmol/L (calc) Sterile Nonytrogenic Single dose container Additives may be incompatible Consult with pharmacist if available When introducing additives use aseptic technique Mox thronoughly Do mot	=	[Strength] 1000m; 50g [Description] This product is a clear, coloriess or almost coloriess liquid [Dosage and Administration] Intravenous drip. See the package insert for details.		
STORE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAULTIONS SQUEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERLITY DISCARD IF LEAKS ARE FOUND MUST.	5	For details of Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the puckage insert [Storage] Store in overwap The solution should be clear and should be used		
NOT BE USED IN SERIES CONNECTIONS DO NOT ADMINISTER SIMULTANEOUSLY WITH BOOOD DO NOT USE UNLESS BOLUTION IS CLEAR RX ONLY STORE UNIT IN MOSTURE BARRIER OVERWARP AT ROOM TEMPERATURE (25°C/77°F) UNIT. READY TO USE	6	700 The soundershould be creat and should be used at one time Inspect the inner bag by squeezing it and discard southern if wakage occurs License Number: H19893151		
AVOID EXCESSIVE HEAT SEE INSERT VIAFLEX CONTABLE PL 148 PLASTIC	7	[Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388; Tingdha Road, Jinshan District, Shanghai		
BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC.		OTIN Barcode Area		
FOR PRODUCT INFORMATION 1-800-933-0303	=	900		
Protes	8	LOT MFG		
BAXTER BAXTICARE CORPORATION DEFINELD IL 60015 USA Made in USA	9	EXP		

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Table 5 Key differences between FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection

	FDA-approved product	Imported product from Shanghai, China
Product name	10% Dextrose Injection USP	10% Glucose Injection
Label volume	250 mL	250 mL
Language of the Labels	English	English
Indications	Dextrose Injection, USP is indicated as a source of water and calories.	Glucose Injection is indicated as a source of water and calories.
Active ingredients	Each 100 mL contains 10 g Dextrose Hydrous USP	Each 100 mL contains 10 g Anhydrous Glucose
Additional information	pH 4.0 (3.2 to 6.5) Osmolarity 505 mOsmol/L (calc)	pH 4.0 (3.2 to 6.5) Osmolarity 555 mOsmol/L (calc)
Caloric content	340 kcal/L	400 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
Medication and Administration port closures	Contains medication port and administration port; Pull off port protector (blue color), right side	Contains medication port and administration port; Twist off port Protector (white color), left side

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Table 6 Label images of FDA-approved 10% Dextrose Injection USP and imported 10% Glucose Injection

US-FDA approved product	Imported product from Shanghai, China
10% Dextrose Injection USP	10% Glucose Injection
Label Color: Black. Barcode not shown.	Label Color: Black. Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.
LOT EXP	Baxter® A6C0162US
2B0162	Daxter A6C01620S
10% Dextrose	GLUCOSE INJECTION
Injection USP $\overline{_{50}}$	/100V
250 mL EACH 100 mL CONTANS 10 g DEXTROBE HYDROUG USP pH 4.0 (3.2 to 6.5) HYDROGO MORALPHY 505 MODINOUL (OAC) STEWLE NOSPYROGRAMS SHALL DOSE CONTANTAL ACCURITIES MAY BE	50 250ml (10%)
PROCRIPATRIE CONSULT WITH PRAMMACEIT IF AVALABLE WHEN INTRODUCING ADDITIVES USE ASSETTIC TROUNDAGE MIX THORROUGHLY DO NOT STORIE DOSAGE INTRAVENOUSLY AS DIRECTION SO A PHYSICIAN SEE CONSCITIONS CAUTIONS SQUIEZE AND INSPECT INNER AND WHICH MAINTAINER INSPECT INNER AND WHICH MAINTAINER	[Strength] 250ml; 25g [Oescripton] This product is a clear, colorless or almost colorless fluid [Oosage and Administration] Intravenous drip. See the package insert for details. For details of [Indications], [Adverse Reactions],
PRODUCT STITRELTY DISCORD IF LEAVE AND FOUND MUST NOT BE USED IN SERVES CONNECTIONS DO NOT ADMINISTER SMALLTANGOUSLY WITH BLOOD DO NOT USES UNLESS BOLLOON IS CLEAR P. R. ONLY	[Contraindications], and [Precautions], please refer to the package insert (Storage) Store in overwrap The solution should be clear and should be used up at one time
STORE UNIT IN MOISTURE BARRIER 200 OVERWAR AT ROOM TEMPERATURE (25°C77"F) UNTE, REGIOT TO USE AVOID EXCESSARE HEAT SEE MORRY	Inspect the inner bag by squeezing it and discard solution if leakage occurs License Number: H19994003 [[Orug Marketing Authorization Holder] [Manufacturer]
VIAFLEX CONTAINER PL 146 FLASTIC BAXTER VIAFLEX AND PL 146 AVE TRADEMAND OF BAXTER INTERNATIONS. INC.	Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingchu Road, Jinshan District, Shanghai GTIN Barcode Area
BAXTER HEALTHCAME CORPORATION DERIVED IL 60015 USA 1-800-933-0303	
	LOT MFG
	EXP

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Table 7 Key differences between FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium Chloride Injection

100	FDA-approved product	Imported product from Shanghai, China
Product name	5% Dextrose and 0.9% Sodium Chloride Injection USP	5% Glucose and 0.9% Sodium Chloride Injection
Label volume	1000 mL	1000 mL
Language of the Labels	English	English
Indications	Dextrose and Sodium Chloride Injection, USP is indicated as a source of fluid and electrolyte replenishment and caloric supply.	Dextrose and Sodium Chloride Injection is indicated as a source of fluid and electrolyte replenishment and caloric supply.
Active ingredients	Each 100 mL contains 5 g Dextrose Hydrous USP and 900 mg Sodium Chloride USP	Each 100 mL contains 5 g Anhydrous Glucose and 900 mg Sodium Chloride
Additional information	pH 4.0 (3.2 to 6.5) Osmolarity 560 mOsmol/L (calc)	pH 4.0 (3.2 to 6.5) Osmolarity 585 mOsm/L (calc)
Caloric content	170 kcal/L	200 kcal/L
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 15°C/59°F. to 30°C/86°F.
Container type	VIAFLEX (PVC)	IVINA (non-PVC)
ment alexander		Contains medication port and administration port; Twist off port protector (white color), left side

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Table 8 Label images of FDA-approved 5% Dextrose/0.9% Sodium Chloride Injection USP and imported 5% Glucose/0.9% Sodium Chloride Injection

FDA-approved product	Imported product from Shanghai, China
5% Dextrose and 0.9% Sodium Chloride Injection USP	5% Glucose and 0.9% Sodium Chloride Injection
Label Color: Black. Barcode not shown.	Label Color: Black. Imported product contains the NDC number, which is not yet shown below. Barcode location is shown and will contain a linear barcode with human readable information.
LOT EXP ② 281064 NDC 0338-0093-04	100 Baxter® A6C1064US
ī	5% GLUCOSE AND 0.9% SODIUM CHLORIDE INJECTION
5% Dextrose and 2 0.9% Sodium Chloride 3 Injection USP 3	300 1000ml 5% 0.9% SODIUM CHLORIDE
1000 mL EACH 100 mL, CONTAINS 5 g D'EXTHOSE HYCHOUS USP 900 mg SCOUM CHLORICE USP pH 4.0 (3.2 to 6.5) mEgl. SCOUM 154 CHLORICE 154 HYCHOCOM COSKOLANT 650 mODERNAL (SALC) STERLE NOMYPROLENC SIMILE DOISE CONTAINER ADDITINES WAY SE INCOMPATIBLE CONSULT WITH	[Strength] 1000ml: GLUCOSE 50g AND SODUM CHLORIDE 9g [Description] This product is a clear, colorless liquid [Dosage and Administration] infravenous step See the package insert for details For details of Illustrational, [Adverse Reactions].
PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX THORROUGHLY DO NOT STORE DOSAGE INTRAVENCUS/ AS DEPICTED BY A PHYRICAN SEC	[Contraindications], and [Precautions], please refer to the package insert [Storage] Store in overwrap The solution should be clear and should be used
DIRECTIONS CANTONS SQUEEZ AND INSTRUCT WHER AND WHICH MANY PRODUCT STERRITY DISCARD IN LEAST AND FOUND MINET NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR IR DALY STORE UNIT IN MOISTURE SARRIER OVERHIRAP AT ROOM TEMPERATURE (25°C/37°F) UNIT, RADOY TO USE	The solution should be clear and should be used up at one time inspect the inner bag by squeezing it and discard solution if leakage occurs License Number: H19994068 [Drug Marketing Authorization Holder] [Manufacturer]
AVOID EXCESSIVE HEAT SEE INSERT VIAFLEX CONTAINED. BUTTH VIAFLEX AND PL 146 ARE TRADEMANS OF BUTTH ENTREMEDIANAL PLC.	Name: Baxter Healthcare (Shangha) Co., Ltd. Address: No. 388, Yingzhu Road, Jinshan District, Shanghai GTIN Barcode Area
BAXTEF BARTEN MEALTHCARE COMPONATION DISSIPHIED IL 60015 USA Massi in USA 1-800-933-0303 1-800-933-0303	900 LOT MFG

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PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

SODIUM CHLORIDE INJECTION

50

250ml



[Strength] 250ml: 2.25g

100 [Description] This product is a clear, colorless liquid

[Dosage and Administration] Intravenous drip See the package insert for details

For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert

[Storage] Store in overwrap

150 The solution should be clear and should be used up at one time

Inspect the inner bag by squeezing it and discard solution if leakage occurs

License Number: H19994066

(AA)

200

[Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd.

Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

GTIN Barcode Area

LOT

MFG

EXP

Container Label

Baxter Logo Trademark

A6C1322US

SODIUM CHLORIDE INJECTION

50

100

150

200

250ml

0.9% Sodium Chloride

[Strength] 250ml: 2.25g

[Description] This product is a clear, colorless liquid

[Dosage and Administration] Intravenous drip See the package

insert for details

For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert

[Storage] Store in overwrap

The solution should be clear and should be used up at one time Inspect the inner bag by squeezing it and discard solution if leakage occurs License Number: H19994066

AA

[Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd.

Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

GTIN Barcode Area

LOT

MFG

EXP

SODIUM CHLORIDE INJECTION

100

500ml



200

[Strength] 500ml: 4.5g

[Description] This product is a clear, colorless liquid

[Dosage and Administration] Intravenous drip See the package

insert for details

For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert

[Storage] Store in overwrap

300

The solution should be clear and should be used up at one time

Inspect the inner bag by squeezing it and discard solution if leakage occurs

License Number: H19983148



[Drug Marketing Authorization Holder] [Manufacturer]

Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

400

GTIN Barcode Area

LOT

MFG

EXP

Container Label

Baxter Logo Trademark

A6C1323US

SODIUM CHLORIDE INJECTION

100

200

300

400

500ml

0.9% Sodium Chloride

[Strength] 500ml: 4.5g

[Description] This product is a clear, colorless liquid

[Dosage and Administration] Intravenous drip See the package insert for details
For details of [Indications], [Adverse Reactions],
[Contraindications], and [Precautions], please refer to the package insert

[Storage] Store in overwrap

The solution should be clear and should be used up at one time Inspect the inner bag by squeezing it and discard solution if leakage occurs License Number: H19983148

AA

[Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

GTIN Barcode Area

LOT MFG EXP

Baxter® 100 A6C1324US SODIUM CHLORIDE INJECTION 200 300 1000ml 400 [Strength] 1000ml: 9g [Description] This product is a clear, colorless liquid 500 [Dosage and Administration] Intravenous drip See the package insert for details For details of [Indications], [Adverse Reactions], [Contraindications], and [Precautions], please refer to the package insert 600 [Storage] Store in overwrap The solution should be clear and should be used up at one time Inspect the inner bag by squeezing it and discard solution if leakage occurs 700 License Number: H19983149 [Drug Marketing Authorization Holder] [Manufacturer] Name: Baxter Healthcare (Shanghai) Co., Ltd. Address: No. 388, Tingzhu Road, Jinshan District, Shanghai 800 GTIN Barcode Area 900 LOT MFG

Container Label

EXP

Baxter Logo Trademark

A6C1324US

SODIUM CHLORIDE INJECTION

100

200

300

<u>400</u>

500

<u>600</u>

<u>700</u>

800

900

1000ml 0.9% Sodium Chloride

[Strength] 1000ml: 9g

[Description] This product is a clear, colorless liquid

[Dosage and Administration] Intravenous drip See the package

insert for details

For details of [Indications], [Adverse Reactions],

[Contraindications], and [Precautions], please refer to the

package insert

[Storage] Store in overwrap

The solution should be clear and should be used up at one time

Inspect the inner bag by squeezing it and discard

solution if leakage occurs License Number: H19983149

AA

[Drug Marketing Authorization Holder] [Manufacturer]

Name: Baxter Healthcare (Shanghai) Co., Ltd.

Address: No. 388, Tingzhu Road, Jinshan District, Shanghai

GTIN Barcode Area

LOT

MFG

EXP

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-9791
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
	SODIUM CHLORIDE	9 g in 1000 mL		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-9791- 40	40 in 1 CARTON	10/21/2024	
1	NDC:0338-9791- 01	250 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	10/21/2024		
	Application Number or	Application Number or Marketing Start Monograph Citation Date	

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:0338-97			NDC:0338-9793
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 g in 1000 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		

ı	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0338-9793-	12 in 1 CARTON	10/21/2024	
	NDC:0338-9793-	1000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or	Marketing Start	Marketing End
	Monograph Citation	Date	Date

Unapproved drug for use in drug shortage	<u> </u>	10/21/2024	

SODIUM CHLORIDE

sodium chloride injection, solution

Product	Intorm	ation

Product TypeHUMAN PRESCRIPTION DRUGItem Code (Source)NDC:0338-9808

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37,	SODIUM	9 g
CHLORIDE ION - UNII:Q32ZN48698)	CHLORIDE	in 1000 mL

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-9808- 24	24 in 1 CARTON	10/21/2024	
	NDC:0338-9808- 01	500 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or	Marketing Start	Marketing End
	Monograph Citation	Date	Date
Unapproved drug for use in drug shortage		10/21/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment			
Na me	Address	ID/FEI	Business Operations
Baxter Healthcare (Shanghai) Co. Ltd.		527191860	MANUFACTURE(0338-9791, 0338-9793, 0338-9808)

Revised: 10/2024 Baxter Healthcare Corporation